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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---|----------------------|---------------------|------------------|
| 10/815,000 | 03/31/2004 | Chunlin Yang | DEP-5286 | 1332 |
| 27777 PHILIP S. JOH | 7590 03/10/200 NSON | EXAMINER | | |
| JOHNSON & J | | KAM, CHIH MIN | | |
| | N & JOHNSON PLAZ VICK, NJ 08933-7003 | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/10/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | | |
|-----------------|--------------|--|--|
| 10/815,000 | YANG ET AL. | | |
| Examiner | Art Unit | | |
| CHIH-MIN KAM | 1656 | | |

| | CHIH-MIN KAM | 1656 | |
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| The MAILING DATE of this communication appe | ars on the cover sheet with the | correspondence add | ress |
| THE REPLY FILED <u>04 February 2009</u> FAILS TO PLACE THIS . | APPLICATION IN CONDITION FO | R ALLOWANCE. | |
| The reply was filed after a final rejection, but prior to or on application, applicant must timely file one of the following application in condition for allowance; (2) a Notice of Apperior Continued Examination (RCE) in compliance with 37 C periods: | the same day as filing a Notice of replies: (1) an amendment, affidavi eal (with appeal fee) in compliance | Appeal. To avoid abar t, or other evidence, w with 37 CFR 41.31; or | hich places the (3) a Request |
| a) The period for reply expires <u>6</u> months from the mailing date | of the final rejection. | | |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire to Examiner Note: If box 1 is checked, check either box (a) or (MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f) | ater than SIX MONTHS from the mailing b). ONLY CHECK BOX (b) WHEN THE c). | g date of the final rejection FIRST REPLY WAS FII | n. LED WITHIN TWO |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date of have been filed is the date for purposes of determining the period of extunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL | ension and the corresponding amount hortened statutory period for reply origi | of the fee. The appropria nally set in the final Offic | ate extension fee e action; or (2) as |
| The Notice of Appeal was filed on A brief in comp filing the Notice of Appeal (37 CFR 41.37(a)), or any exter Notice of Appeal has been filed, any reply must be filed wi | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of the | |
| AMENDMENTS | | | |
| 3. The proposed amendment(s) filed after a final rejection, be (a) They raise new issues that would require further core (b) They raise the issue of new matter (see NOTE below (c) They are not deemed to place the application in between appeal; and/or (d) They present additional claims without canceling a content of the proposed amendment of the propo | nsideration and/or search (see NO w); ter form for appeal by materially red | ΓE below); ducing or simplifying the | |
| NOTE: (See 37 CFR 1.116 and 41.33(a)). | | | |
| 4. ☐ The amendments are not in compliance with 37 CFR 1.12 5. ☐ Applicant's reply has overcome the following rejection(s): 6. ☐ Newly proposed or amended claim(s) would be all | See Continuation Sheet. | | |
| non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) [how the new or amended claims would be rejected is prov The status of the claim(s) is (or will be) as follows: Claim(s) allowed: | | l be entered and an ex | xplanation of |
| Claim(s) objected to: Claim(s) rejected: <u>1-14</u> . Claim(s) withdrawn from consideration: <u>15-23</u> . AFFIDAVIT OR OTHER EVIDENCE | | | |
| The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | | | |
| 9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary | vercome <u>all</u> rejections under appear and was not earlier presented. Se | al and/or appellant fails see 37 CFR 41.33(d)(1) | s to provide a |
| 10. ☐ The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER | n of the status of the claims after e | ntry is below or attach | ed. |
| The request for reconsideration has been considered but <u>See Continuation Sheet.</u> | does NOT place the application in | condition for allowan | ce because: |
| 12. Note the attached Information <i>Disclosure Statement</i> (s). (13. Other: | PTO/SB/08) Paper No(s) | | |
| | /Chih-Min Kam/ Primary Examiner, Art U | nit 1656 | |

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of 1-14 under 35 U.S.C. 112, second paragraph.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's reply does not overcome the rejection of claims 1-6, 8, 9, 11, 12 and 14 under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (U.S. 2002/0183855; see pages 4-5 of Office Action dated 8/4/08); and the rejection of claims 1, 6, 7, 10 and 13 as being unpatentable over Yamamoto et al. (U.S. 2002/0183855) in view of Silver et al. (U.S. Patent5,532,2170) (see pages 5-6 of Office Action dated 8/4/08). In the amendment filed 2/4/09, claims 1 and 4 have been amended.

Applicants indicate claim 1 has been amended to clarify the claimed composition is "flowable", and Yamamoto does not teach a flowable composition. Yamamoto discloses a composition with "a compressible shape memory" (see [0056]). The matrix maintains its integrity and shape after hydration. The hydrated matrix can be compressed and manually inserted through a narrow opening but returns to its original size and shape on rehydration. Whereas, the claimed invention is not compressed in order to flow through the cannula. Therefore, Yamamoto does not teach or suggest the claimed invention. Regarding the obviousness rejection, applicants indicate Yamamoto does not anticipate nor render obvious the claimed invention as argued. Applicants further submit that Silver et al. does not remedy the defects of Yamamoto. Thus, the combination of these references does not arrive at Applicants' claimed invention. Therefore, the rejection should be withdrawn.

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. Yamamoto et al. teach the mineralized collagen matrix can be easily hydrated by placing the matrix in fluid, and the matix maintains its integrety and shape after hydration (paragraph [0056]). Yamamoto et al. also indicate the matrix can be compressed into a delivery vehicle such as a cannula and the delivery vehicle can be introduced at the site of desired tissue growth (paragraph [0034]). Applicants argue that the claimed invention is not compressed in order to flow through the cannula, however, the specification recites "the term flowable is used herein to denote that physical state where the compositions will flow upon application of force required to administer such composition through a cannula of a medical device as device as described herein below" (page 5, line 25, to page 6, line 1). Since both the instant application and Yamamoto et al. teach the composition contains the same materials and can be delivered through a cannula upon application of force to administer such composition, thus, the composition taught by Yamamoto et al. is not different from the claimed composition. Therefore, the 102 (b) rejection is maintained.

Regarding the obviousness rejection, Yamamoto et al. teach the composition described above, and Silver et al. teach a bone replacement structure that has demineralized matrix, where the collagen fibers can have diameters of less than a micron and up to several millimers, where the teachings of Silver et al. would remedy the defects of Yamamoto as indicated in the previous Office Action. Therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/ Primary Patent Examiner

CMK March 9, 2009